REMARKS

Claims 1-7 and 16-22 are pending. By way of the present amendment, new claims 23-27 are added and claims 1-7 and 16-22 are cancelled without prejudice to or disclaimer of the underlying subject matter. Claims 8-15 were cancelled without prejudice to or disclaimer of the underlying subject matter in amendments filed April 18, 2002. Support for the foregoing new claims can be found throughout the specification and claims as originally filed, for example on page 15, line 10 through page 16, line 6 and page 76, line 3 through page 78, line 8. No new matter enters by way of this amendment. Upon entry of the foregoing amendment, claims 23-27 will be pending.

1. Request for Continued Examination

The instant application was appealed to the Board of Patent Appeals and Interferences ("Board") on September 23, 2002. The appeal was suspended at the request of the Applicants on September 29, 2004, pending the U.S. Court of Appeals for the Federal Circuit's disposition of *In re Fisher*. Applicants file herewith a Request for Continued Examination under 37 C.F.R. § 1.114.

2. Claim Rejections – 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-7 and 16-22 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Final Action at pages 2-4. Applicants note that claims 1-7 and 16-22 have been cancelled without prejudice to or

disclaimer of the underlying subject matter, however, Applicants submit that new claims 23-27 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

Despite the Examiner's admission that "claims limited to nucleic acid of SEQ ID NO 2 would meet the written description and enablement provisions of 35 U.S.C. §112, first paragraph," the Examiner maintains the rejection of claims 1-7 and 16-22 under 35 U.S.C. § 112, first paragraph as allegedly not being supported by an adequate written description. Final Action at page 3. In support of this rejection, the Examiner asserts that "the claims are directed to nucleic acids comprising said SEQ ID NO: [2] (or, rather, comprising fragments thereof) and thus encompass products such as full-length DNAs and genes". *Id.* The bases for the Examiner's challenge are that (1) the specification allegedly does not "describe any single representative of the genus of fragments of 30-300 nucleotides of SEQ ID NO: 2", and (2) that the use of the transitional language "comprising" encompasses products that have not been described in the specification." *Id.* at pages 3-4. These are not proper bases for a written description rejection of a "comprising" claim. If they were, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565,

1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NO: 2, complements and variations thereof, and fragments of thereof, and therefore, the claimed invention.

Applicants have provided the nucleotide sequence required by the claims, *i.e.*, SEQ ID NO: 2, as well as, for example, nucleic acid sequences having the recited percent sequence identity (*see, e.g.*, specification at page 15, line 10 through page 16, line 6), and vectors comprising the nucleic acid sequence (*see, e.g.,* specification at page 59, line 7 to page 68, line 6) and have thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules. It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The Examiner argues that the specification does not "describe any single representative of the genus of fragments of 30-300 nucleotides of SEQ ID NO: 2". The specification provides ample support for the fragments of 30-300 nucleotides of SEQ ID NO: 2, for example at page 82, lines 10-14. Although Applicants disagree with the Examiner's allegation, Applicants note that claims 1-7 and 16-22 have been cancelled without prejudice to or disclaimer of the underlying subject matter, and new claims 23-27 do not recite "a fragment from about 30 to about 300 nucleotides."

Furthermore, the present application describes more than just the nucleic acid sequence recited by the claims (SEQ ID NO: 2), for example, it describes vectors comprising the claimed nucleic acid molecules (specification at page 59, line 7 to page 68, line 6), nucleic acid sequences having between 100% and 90% sequence identity with SEQ ID NO: 2 (*see, e.g.,* specification at page 15, line 10 through page 16, line 6) and describes how to make the nucleotide sequence and the libraries from which it was originally purified. *See* Example 1, beginning at page 83, *et seq.* Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequence is readily envisioned by one of ordinary skill in the art upon reading the present specification, in particular at page 13, lines 15-19 (describing sequences with labels to facilitate detection), page 19, line 22 through page 20, line 30 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules), Example 1 at page 83, line 18 through page 87, line 18 (describing methods to generate BAC libraries from genomic including the claimed nucleic acid molecules), page 58, line 10 through page 59, line 2 (describing site directed mutagenesis), and page 82, lines 10-14 (describing sequences containing from about 30 to 300 nucleotide residues). Moreover, it is well established that claims "may be broader than the specific

embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (CCPA 1981)).

The Examiner asserts that "[t]he specification describes only SEQ ID NO: 2 and no other longer sequence containing them." Final Action at page 3. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description where a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 2. The respective common structural feature (the nucleotide sequence, variations and complements thereof and fragments of any) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as a gene sequence contains the nucleotide sequence of SEQ ID NO: 2, then it is a member of the claimed genus of nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 2. If a nucleic acid molecule does not contain a nucleic acid sequence within the recited percent sequence identity range with the nucleic acid sequence of SEQ ID NO: 2, then it is not a member of that claimed genus. The presence of other nucleotides at either

end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 2 or it does not. One skilled in the art would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences.

As such, claims 1-7 and 16-22 satisfy the written description, however, Applicants note that claims 1-7 and 16-22 have been cancelled without prejudice to or disclaimer of the underlying subject matter. Accordingly, the rejection of claims 1-7 and 16-22 under 35 U.S.C. § 112, first paragraph is moot. However, for the reasons set forth above, new claims 23-27 also satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

3. Claim Rejections – 35 U.S.C. § 101

Claims 1-7 and 16-22 stand rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either a "specific, substantial, and credible utility or, in the alternative, a well-established utility." Final Action at pages 4-6. As claims 1-7 and 16-22 have been cancelled without prejudice to or disclaimer to the underlying subject matter, Applicants respectfully submit that new claims 23-27 satisfy the 35 U.S.C. § 101 utility requirement.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, plants, gene mapping, isolation of homologous sequences, detection of gene expression." Office Action at page 4. The Examiner asserts that "[t]hese are non-

specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid of SEQ ID NO. 2 being claimed." *Id.* at pages 4-5.

The Federal Circuit has recently reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, 1371, 76 U.S.P.Q.2d 1225, 1229 (Fed. Cir. 2005)(citing *Brenner*, 383 U.S. at 534-35)(emphasis in original). The Court noted that since "*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371, 220 U.S.P.Q.2d at page 1230. First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public*." *Id.* (emphasis original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

Applicants have met this test – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, use for reducing expression of an endogenous gene. *See, e.g.* Specification at page 76, line 3 through page 78, line 8. The present specification discloses that the claimed nucleic acid molecules can be used to transform plants (*see, e.g.,* specification at page 59, line 7 through page 75, line 12); and to reduce the expression of a desired protein (*see, e.g.,* specification at page 76, line 3 through page 78, line 8). This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

4. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1-7 and 16-22 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Office Action at page 6. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. As claims 1-7 and 16-22 have been cancelled without prejudice to or disclaimer of the underlying subject, Applicants respectfully submit that the rejection of claims 1-7 and 16-22 is moot. In addition, for the reasons set forth above with regard to utility, new claims 23-27 are enabled.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned at (202) 942-5000 should any additional information be necessary for allowance.

Respectfully submitted,

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